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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,246	09/21/2000	Gustav Hagen	LEA32805	7783

7590  
Jeffrey M Greenman  
Bayer Corporation  
400 Morgan Lane  
West Haven, CT 06516

09/30/2003

EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

13

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/582,246

Applicant(s)

HAGEN ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I-XVII, claim(s) 1-6, 8 and 13, drawn to nucleic acids comprising regulatory DNA sequences for the human catalytic telomerase subunit and host cells and medicaments comprising said nucleic acids wherein each of Groups I-XVII are distinguished in being directed to the nucleic acid set forth as SEQ ID NO: 4-20 respectively.

Group XVIII-XXXIV, claim(s) 7, drawn to a method of using the nucleic acid of Group I for preparing medicaments.

Group XXXV-LI, claim(s) 9, drawn to a method for identifying substances that effect the promoter activity of the nucleic acid of Group I comprising adding a candidate substance to a host cell said nucleic acid.

Group LII-LXVIII, claim(s) 10, drawn to a method for identifying factors that bind specifically to the nucleic acid of Group I comprising screening an expression library.

Group LXIX-LXXXV, claim(s) 11, drawn to a transgenic animal comprising the nucleic acid of Group I.

Group LXXXVI-CII, claim(s) 12, drawn to a method for diagnosing telomerase-associated conditions in a patient comprising incubating body fluids from a patient with a recombinant construct comprising a nucleic acid of Groups I-XVII.

The inventions listed as Groups I-CII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The products and methods of Groups I-XVII, XVIII-XXXIV, XXXV-LI, LII-LXVIII, LXIX-LXXXV or LXXXVI-CII, are all distinguished from one another in being directed to nucleic

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acids comprising distinct structural and functional characteristics, animals comprising nucleic acids comprising distinct structural and functional characteristics or methods of using nucleic acids comprising distinct structural and functional characteristics. Section (f)(i)(B)(1) of Annex B of the Administrative Instructions requires that all alternatives of a Markush group have a common structure and/or function. Although the chemical compounds of claim 2 generally share the function of regulating expression of the catalytic telomerase subunit, each of the nucleic acids comprises a unique structure. Furthermore, regulatory role of each of the nucleic acids is functionally distinct from the others. Thus, the nucleic acids lack a unifying special technical feature.

Further, PCT Rule 13.2 requires that unity of invention exists only when there is a shared same or corresponding technical feature among the claimed inventions. All of the Groups are directed to products comprising nucleic acids obtained from the human catalytic telomerase gene and methods of using said nucleic acids, but each group has a different special technical feature not shared by the remaining groups. Although the transgenic animal of Groups LXIX-LXXXV would comprise the nucleic acid of Inventions I-XVII, both the structure and function of the animal as a whole are distinct from the structure and function of any individual nucleic acid comprised within the animal. With regard to the methods of Groups XVIII-XXXIV, XXXV-LI, LII-LXVIII and LXXXVI-CII, each method comprises a unique special technical feature. Groups XVIII-XXXIV have the special technical feature of preparing medicaments, Groups XXXV-LI comprise the special technical feature of adding a candidate substance to a host cell and measuring the effect, Groups LII-LXVIII comprise the special technical feature of screening an expression library and Groups LXXXVI-CII comprise the special technical feature of incubating body fluids from a patient with a nucleic acid.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms

  
**JAMES KETTER**  
**PRIMARY EXAMINER**